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REMARKS

The Examiner's Office Action dated April 12, 2006 has been received and carefully considered.

With respect to the Examiner's Office Action, Applicant has amended Claims 1, 7 and 10. Claims 1, 7 and 10 are the independent claims. Claims 3-5 and 13-17 depend upon Claim1. Claim 6 depend upon Claim 5, Claim 8 depends upon Claim 7 and Claim 9 depends upon Claim 8. Furthermore Claims 11-12 depend upon Claim10. Claims 1, 3-17 remain pending.

**35 U.S.C. §103(a) Rejection of Claims 1, 3-17**

The Examiner rejected Claims 1, 3-17 as allegedly being obvious under 35 U.S.C. §103(a) based on the three way combination of Mease et al., U.S. Patent 6,201,022, McClung, U.S. Patent 6,579,543 and Murad U.S. Patent Application 2003/0007939 (presumably the Examiner inadvertently cited Murad as being U.S. Patent Application 2003/0007930).

The Examiner states: "Mease et al. '011 does not disclose using lavender oil, Sodium PCA or Methyl-Sulfonyl-Methane", "McClung '543 discloses ... methyl-sulfonyl-methane (MSM), lavender and omega-3" and "Murad '930 discloses ... tocopherols (Vitamin E) and moisturizing agents such as sodium PCA and omega-3 which contains gamma-linolenic acid". The Examiner alleges: "based on the disclosure by these references that omega-3, tocopherols, cocoa butter, lavender, sodium PCA and Methyl-Sulfonyl-Methane are used in compositions that aid in relief from burns and other dermatitis conditions, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions aid in relief from burns and other dermatitis conditions. Therefore the artisan would have been motivated to combine omega-3,

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tocopherols, cocoa butter, lavender, sodium PCA and Methyl-Sulfonyl-Methane into a single composition". The Examiner alleges no patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients.

Furthermore, the Examiner states "the references also do not specifically teach the ingredients in the amounts claimed by Applicant". The Examiner alleges "the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize... Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention".

Initially, Applicant has amended independent Claims 1, 7 and 11 merely to make it clear that the features of Applicant's unique and non-obvious compositions are "active against traumatic conditions of the skin".

Applicant respectfully notes that according to MPEP 2144.08, "the determination as to whether a *prima facie* case of obviousness exists should be made on the full record before the Office at the time of the determination. Thus, Office personnel should:

- (A) determine the "scope and content of the prior art";
- (B) ascertain the "differences between the prior art and the claims at issue"; and
- (C) determine "the level of ordinary skill in the pertinent art."

*Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). *Accord*, e.g., *In re Paulsen*, 30 F.3d 1475, 1482, 31 USPQ2d 1671, 1676 (Fed. Cir. 1994)".

Furthermore, obviousness cannot be established by combining references "without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done."

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Ex parte Levingood 28 USPQ2d 1300, 1302 (Bd. Pat. App. & Inter. 1993)

The Examiner alleges that an artisan of ordinary skill "would have been motivated to combine omega-3, tocopherols, cocoa butter, lavender, sodium PCA, and Methyl-Sulfonyl-Methane into a single combination" since one or more of these ingredients were claimed by the three-way cited reference combination.

However, according to MPEP 2144.08, "the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teaching of the references."

Ex parte Clapp, 227 USPQ972, 973 (Bd. Pat. APP. & Inter. 1985),

Applicant thanks the Examiner for a thorough search to determine the scope and content of the prior art, which the Examiner alleges has uncovered numerous ingredients that may comprise a portion of one or more topical formulations suitable for alleviating one or more conditions such as pain relief from burns and sunburns or dermatological conditions caused by aging or extrinsic factors such as sunlight or radiation and wrinkles and sun damaged skin. Applicant respectfully asserts that the ingredients discovered by the Examiner's cited references are merely a list of candidate ingredients which may solve one or more conditions as stated above. The availability of a list of candidate ingredients of known properties does not mean that a person skilled in the art would be motivated to combine Applicant's ingredients to provide Applicant's unique and non-obvious products. Clearly, no prior art cited or found by the Examiner has Applicant's specific combination of ingredients.

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According to MPEP 2144.08 "evidence must be viewed from position of ordinary skill, not of an expert" and "In most cases, the only facts of record pertaining to the level of skill in the art will be found within the prior art reference".

The Examiner's patent citations indicate many different formulations that allegedly are suitable for solving various stated problems. Respectfully, does the Examiner suggest that those cited patents should not have been granted because they also used known ingredients with known properties? Certainly, on the Examiner's own admission, neither the prior art alone or in combination teaches or suggests Applicant's unique and non-obvious features. Instead the Examiner relies on combining three different references to produce a list of ingredients alleged to be known and having known properties to assume that a person skilled in the art would be motivated to combine those ingredients. The Examiner provides no evidence to show why a person skilled in the art would be motivated to combine those specific ingredients other than that they are known and have known properties.

According to case law as shown at MPEP 2144.08, something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination.

Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051, 5 U.S.P.Q.2d 1434, 1438 (Fed. Cir. 1988) (citing Lindemann, Maschinenfrabrik GmbH v. American Hoist and Derrick Co., 730 F2d 1452, 1462, 221 U.S.P.Q. 481, 488 (Fed. Cir. 1984)).

Applicant respectfully contends that in citing this three reference combination obviousness rejection, the Examiner may have fallen into the common trap of hindsight reconstruction, which has been frequently

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denounced by the Federal Circuit as inappropriate to support a finding of obviousness (see MPEP 2144.08).

The obviousness standard, while easy to expound, is sometimes difficult to apply. It requires the decision maker to return to the time the invention was made. "the invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."

Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1050-51, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988) (quoting Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138, 227 U.S.P.Q. 543, 547-548 (Fed. Cir. 1985)).

It is clear from Applicant's discussion above that, absent the "blueprint" of Applicants' disclosure, the prior art has no suggestion or teaching of Applicants' claimed invention. The Federal Circuit has also stated:

It is improper to use the patent as an instruction manual to lead to elements of the prior art (see MPEP 2141.01, 2141.02, 2144.08).

Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1568 (Fed. Cir. 1987).

It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious (see MPEP 2143.01).

In re Fritch, 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992) (citing In re Gorman, 933 F.2d 982, 987, 18 U.S.P.Q.2d 1885, 188 (Fed. Cir. 1991)).

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Respectfully, Applicant submits Applicant's claimed invention is only rendered invalid for obviousness if the Applicant's claimed invention is used as an instruction manual, or template, for modifying the cited prior art. Absent the knowledge gleaned from Applicant's disclosure, there is no suggestion or teaching in the cited prior art or in the general knowledge in the art to support the Examiner's assertion that Applicant's claimed invention would have been obvious to one of ordinary skill in the art. The Federal Circuit has also stated:

When prior art references require selective combination...to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself (see MPEP 2144.08).

Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051, 5 U.S.P.Q.2d 1434, 1438 (Fed.a Cir. 1988) (citing Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985)).

The Examiner has cited no reason for modifying the three cited references to allegedly achieve Applicant's claimed invention other than the knowledge gleaned from Applicants' disclosure. For this reason, Applicant respectfully contends that the Examiner has failed to establish a *prima facie* case of obviousness based on a combination of these three references. To show the invidious nature of hindsight reconstruction, the Federal Circuit has stated:

To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of

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record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher (see MPEP 2143.01, 2143.03, 2144).

*In re Fine*, 837 F2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988) (quoting *W.L. Gore & Assoc. v. Garlic, Inc.*, 721 F.2d 1540, 1553, 220 U.S.P.Q. 303, 312-13 (Fed. Cir. 1983)).

Therefore, Applicant respectfully contends that the Examiner has neither shown a teaching, suggestion nor motivation in any one or more of the three cited references or elsewhere of Applicant's claimed compositions to support a conclusion of obviousness.

Furthermore, the Examiner states "the references also do not specifically teach the ingredients in the amounts claimed by Applicant". The Examiner alleges "the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize... Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention".

Initially, Applicant asserts that the art of formulating requires more than simply routinely optimizing ingredients to achieve one or more result(s).

Furthermore, Applicant respectfully traverses the Examiner's allegations because:

- 1) unexpected results were obtained;
- 2) at least one of the three patents cited by the Examiner actually teach away from Applicant's composition;
- 3) an artisan of ordinary skill would have had no motivation for combining the specific ingredients at the specific concentrations found in

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Applicant's compositions even should the artisan specifically choose these ingredients (a selectivity which goes beyond the definition of a person skilled in the art according to the discussion above).

According to Applicant's specification (see Paragraphs [0016], [0030] and [0040]), Applicant's compositions yielded unexpected results in two separate areas: a) the use of molecularly distilled fish oil allowed high concentrations to be utilized without problematic odors; b) the performance of Applicant's compositions exceeded the additive effects of the ingredients.

Respectfully, Applicant asserts that molecularly distilled fish oil allowed formulation of high concentrations. Fish oil, the source of EPA and DHA, produces an offensive odor when applied to skin as described in Applicant's specification (see Paragraphs [0006]-[0016]). Consequently, Applicant asserts (as disclosed in the detailed Background of the Invention in Applicant's specification) that very few dermatological creams contain fish oil and only in significantly smaller amounts than Applicant's unique and non-obvious claimed compositions. Therefore, a person skilled in the art at the time Applicant made this invention would not have been able to routinely optimize the stated ingredients.

The inventors of the Examiner's cited references were either unaware of this problem or completely ignored it by predominantly used plant fatty acids, such as GLA, rather than those from fish oil (EPA, DHA). Specifically, McClung '543 did not include fish oils in any of three example formulations listed in Table 1. Murad '939 did not use fish oils in any of 14 examples. In Example 1, Mease et al. '022 list eight formulations which were presumably used in the ten clinical examples which follow. Of these eight formulations, only two, Formulations E and F, contain EFA and DHA, presumably from fish oil. The others contain plant GLA as their source of omega fatty acids. Since the ten clinical examples did not specify the formulation used, it is unclear how

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often--or even if--Formulations E and F were used. Of course, one could speculate that a person suffering from neuritic pain might very well endure smelling like a fish in order to alleviate it. Additionally, Mease et al. '022 does not disclose Applicant's compositions in Examples E and F noted above, so the Examiner has relied on two other references to construct an obviousness rejection as noted above.

Applicant submits the discovery that formulating with molecularly distilled fish oil to prevent the complication of offending odors after dermal application was unexpected.

Furthermore, Applicant submits that the performance of Applicant's unique and non-obvious compositions exceeded the additive effects of the ingredients. The combination disclosed in Applicant's specification and in Applicant's claims produce unexpected results (i.e., healing), rather than those anticipated (i.e., pain relief) from the additive effects of the ingredients used, resulting in a "difference in kind." Thus, *In re Waymouth*, 499 F. 2d 1273, 1276, 182 USPQ 290, 293 (CCPA 1974), the court held that unexpected results for a claimed range as compared with the range disclosed in the prior art had been shown by a demonstration of "a marked improvement, over the results achieved under other ratios, as to be classified as a difference in kind, rather than one of degree." Healing a skin condition or preventing it, as disclosed and claimed by Applicant's unique and non-obvious features is markedly different than simple pain relief.

The difference between pain relief and elimination of the underlying medical condition can be readily observed in cancer patients given opiates or other pain relievers. No one would claim that eliminating pain with these drugs heals the cancer or prevents its spread. However, if a combination of pain killers actually eliminated the underlying cancer, the composition would be considered a new and patentable entity due to a "difference in kind."

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Respectfully, Applicant's compositions represent "a difference in kind" since they prevent or heal the underlying medical condition rather than simply alleviating pain.

In comparison, two of the Examiner's prior art citations (McClung '543 and Mease et al. '022) specifically disclose compositions to alleviate pain, specifically that brought about by burns/sunburns and neuritic pain respectively. Simply stated, these compositions relieve symptoms without treating the underlying cause. Applicant's combination, on the other hand, heals or prevents the injury or condition.

For example, dermatomyofibromas are painful and, prior to Applicant's unique and non-obvious invention, treatable only by surgery. A preparation that treated pain might temporarily relieve the itching caused by these growths, but surgery would still be needed to eliminate them. Applicant's combination as supported by Applicant's specification (see Paragraph [0058]), unexpectedly regresses dermatomyofibromas so that surgery is no longer necessary.

Similarly, a combination which relieves the pain of a thermal burn would not be expected to accelerate its healing. However, Applicant's composition as further supported by Applicant's specification (see Paragraph [0057]), results in rapid reestablishment of the dermis.

A combination which numbs an individual to the pain of radiation burn would not be expected to prevent its development. However, as yet further supported by Applicant's specification (see Paragraph [0054]), Applicant's combination does so.

Furthermore, Applicant submits that Murad '939 actually teaches away from Applicant's unique and non-obvious features. Specifically, Murad '939 teaches that hydrogen peroxide enhances the absorption of any dermatological agent, making it more effective in treating, among other things,

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skin conditions. Murad '939 cites a comprehensive list of known dermatological agents that are believed to benefit from combination with hydrogen peroxide.

Using Murad's '939 logic, the Applicant's combination compositions, which includes some of the ingredients in Murad's '939 list, would be expected to have minimal activity because no hydrogen peroxide was present to enhance absorption and biological activity. Applicant respectfully submits that Murad '939 teaches away from Applicant's compositions, which further emphasizes the surprising and unexpected nature of Applicant's unique and non-obvious features.

Stated simply, Applicant asserts that the Examiner has not explained what reasoning would motivate someone skilled in the art to select the specific ingredients and concentrations chosen by the Applicant from the 100+ ingredient list contained collectively in the cited three way reference combination. To sustain a claim of obviousness, Applicant respectfully submits the Examiner should have provided such reasoning. In addition, Applicant's compositions comprise unique and non-obvious features which produce unexpected results in both formulation and performance. Furthermore, Applicant's compositions all contain mixed tocopherols, which are not even mentioned by any of the cited references.

Accordingly, Applicant submits that the Examiner's rejection of Claims 1, 3-17 under 35 U.S.C. §103 (a) has been overcome and respectfully requests withdrawal of this rejection.

Since Applicant previously had four independent claims and twenty-five dependent claims, and now has three independent claims and fourteen dependent claims no fees are due.

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If somehow there are any fees incurred by this Amendment Letter, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1726.

Respectfully submitted,

/Nancy Lord/

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